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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/869,098	09/20/2001	Yukio Toyoda	46342/56000	9857

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EXAMINER	
LEFFERS JR, GERALD G	

ART UNIT	PAPER NUMBER
1636	15

DATE MAILED: 01/13/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/869,098	TOYODA ET AL.	
	Examiner	Art Unit	
	Gerald G Leffers Jr., PhD	1636	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 June 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *12-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 September 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1*.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

Applicant's election with traverse of Group I (claims 1-8 and 11) in Paper No. 14, filed 6/30/2003, is acknowledged. The traversal is on the ground(s) that there would be no undue search burden in examining the different groups together. This is not found persuasive because the instant application is a 371 application and is not subject to the U.S. rules for restriction practice. As indicated in the requirement mailed 6/9/2003 as Paper No. 13, the different groups were restricted based upon a lack of a common special technical feature. However, upon further review, it is apparent that the phrase "use of the transformant" comprising the recombinant vector of the invention necessarily features the identification of compounds that modulate the structural/functional characteristics of the promoter region identified by applicants. Therefore, claims 1-11 have been rejoined. The requirement for claims 12-14 remains in force and claims 12-14 remain withdrawn from consideration as being directed to nonelected inventions for reasons of record.

The requirement is still deemed proper and is therefore made FINAL.

Information Disclosure Statement

Receipt is acknowledged of a pair of information disclosure statements, filed 6/21/01 and 10/7/03, respectively. The signed and initialed PTO Form 1449 for the earlier IDS has been mailed with this action.

The information disclosure statement filed 10/7/2002 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that

portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. If applicants wish the cited references to be considered, a new IDS comprising each reference must be submitted.

Drawings

New corrected drawings are required in this application because parts of the same sequence are presented in separate figures (i.e. SEQ ID NO: 1 has been presented as part of Figures 1-6). It would be remedial to amend the drawings to include SEQ ID NO: 1 as part of a single figure with multiple parts (i.e. parts A-F). In addition, applicants will need to amend the Brief Description of the Drawings to correspond to the amended drawings. Applicant is advised to employ the services of a competent patent draftsperson outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Sequence Compliance

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because sequences were set forth that lack sequence identifiers and no computer readable format (CRF) was filed. These sequences include **the sequences present in the Figures (i.e. Figures 1-6) and**

the primer sequences in the working examples. Receipt is acknowledged of a paper filed 21 June 2001 in which a paper copy of the sequence listing, CRF and attorney's statement were filed. However, there is no record of a CRF in the file. It is necessary for applicants to submit a new CRF, paper copy and attorney's statement regarding similarity of the two and new matter. If the Sequence Listing required for the instant application is identical to that of another application, a letter may be submitted requesting transfer of the previously filed sequence information to the instant application. For a sample letter requesting transfer of sequence information, refer to MPEP § 2422.05. Additionally, it is often convenient to identify sequences in figures by amending the Brief Description of the Drawings section (see MPEP § 2422.02).

Applicants are required to comply with all of the requirements of 37 CFR 1.821 through 1.825. Any response to this office action that fails to meet all of these requirements will be considered non-responsive. The nature of the noncompliance with the requirements of 37 C.F.R. 1.821 through 1.825 did not preclude the continued examination of the application on the merits, the results of which are communicated below.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, the abstract is more than one paragraph in length and is much longer than 150 words.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Each of the claims is directed to a DNA containing an uncoupling protein-2 (UCP-2) promoter region containing a regulator sequence. However, there is no indication in the claims that the "hand of man" is present in the claimed invention. Therefore, the claims improperly read on products of nature and are thus directed to non-statutory subject matter. It would be remedial to amend the claims to read "an isolated DNA".

Claims 8-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 11 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claim 11 is improperly directed to both a composition (i.e. a "kit") and a method (i.e. "characterized by the use of").

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

There is no clear and positive prior antecedent basis for the term "the regulator sequence" in claims 1-3. As disclosed in the instant specification, the upstream regulatory region for the UCP-2 gene comprises multiple regulatory factor binding sites. Thus it is unclear which of these regulatory sequences, or the entire upstream sequence, is encompassed by the cited phrase.

Claims 8-10 provide for the use of a transformant comprising a recombinant vector of the invention in order to screen test compounds for their ability to modulate the expression of operatively linked sequences, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 10 is vague and indefinite in that it is unclear whether the compound to be identified is to necessarily possess all of the activities recited in the claim or must only possess one of the activities. It would appear, based upon reading the specification, that it would be remedial to amend the claim to include proper Markush group language such that the claimed method identifies a compound that necessarily has one of the recited activities.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 8-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement is considered in view of the Wands factors (MPEP 2164.01(A)). These include: nature of the invention, breadth of the claims, guidance of the specification, the existence of working examples, state of the art, predictability of the art and the amount of experimentation necessary. All of the Wands factors have been considered with regard to the instant claims, with the most relevant factors discussed below.

Nature of the invention: The nature of the invention is complex, involving the use of a transformant comprising a human UCP-2 promoter region to identify compounds that, at a minimum modulate expression of an operatively linked coding sequence (e.g. the coding sequence for the human UCP-2 gene).

Breadth of the claims: The methods encompass embodiments wherein the compound affects thermal regulation of body temperature, treats obesity, depression, hyperlipemia and/or is antipyretic.

Guidance of the specification/ The existence of working examples: The specification characterizes an ~6 kb region upstream of the human UCP-2 gene. The specification teaches the UCP-2 gene is thought to play a role in human obesity.

No working examples are provided for testing any compound of any type to determine its effect on expression from the identified UCP-2 promoter in human cells. No significant guidance is provided by applicants with regard to the type of compounds that are likely to have an effect on the promoter of the UCP-2 gene in human cells.

State of the art/Predictability of the art: The prior art does not appear to teach any compounds that would reasonably be expected to have an effect on the UCP-2 promoter in human cells.

The amount of experimentation necessary: Applicants have merely provided an assay (e.g. reporter gene activity) for identifying compounds that may modulate UCP-2 promoter activity in human cells without providing any significant guidance with regard to the production of compounds that can be reasonably expected to exhibit such activity. Therefore, one would have to practice undue, unpredictable experimentation in a trial-and-error manner in order to identify, if possible, compounds having the recited activities. Nor is there any convincing correlation between the UCP-2 protein and the recited activities (e.g. diabetes, depression, hyperlipemia) such that identification of a compound that modulates UCP-2 expression would necessarily identify a modulator of these activities.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Amaral et al (U.S. Patent No. 5,807,740 issued 9/15/1998) or Amaral et al (U.S. Patent No. 5,849,514 issued 12/15/1998).

Both patents disclose DNA containing a promoter region which includes a USP-2 regulator sequence and has a nucleotide sequence that coincides with bases 1762 to 2280 of SEQ ID NO: 1 (e.g. a "part thereof as in claim 4). In particular, cells transformed with UCP-2 promoters operably linked to reporter genes are taught for use in drug screening assays (e.g. Abstract, columns 3-4).

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gerald G Leffers Jr., PhD whose telephone number is (703) 308-6232. The examiner can normally be reached on 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Gerald G Leffers Jr., PhD
Primary Examiner
Art Unit 1636

Ggl